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IS 7434 (1987): Retractor, Scapula, Tudor Edward's Pattern
[MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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“Knowledge is such a treasure which cannot be stolen”

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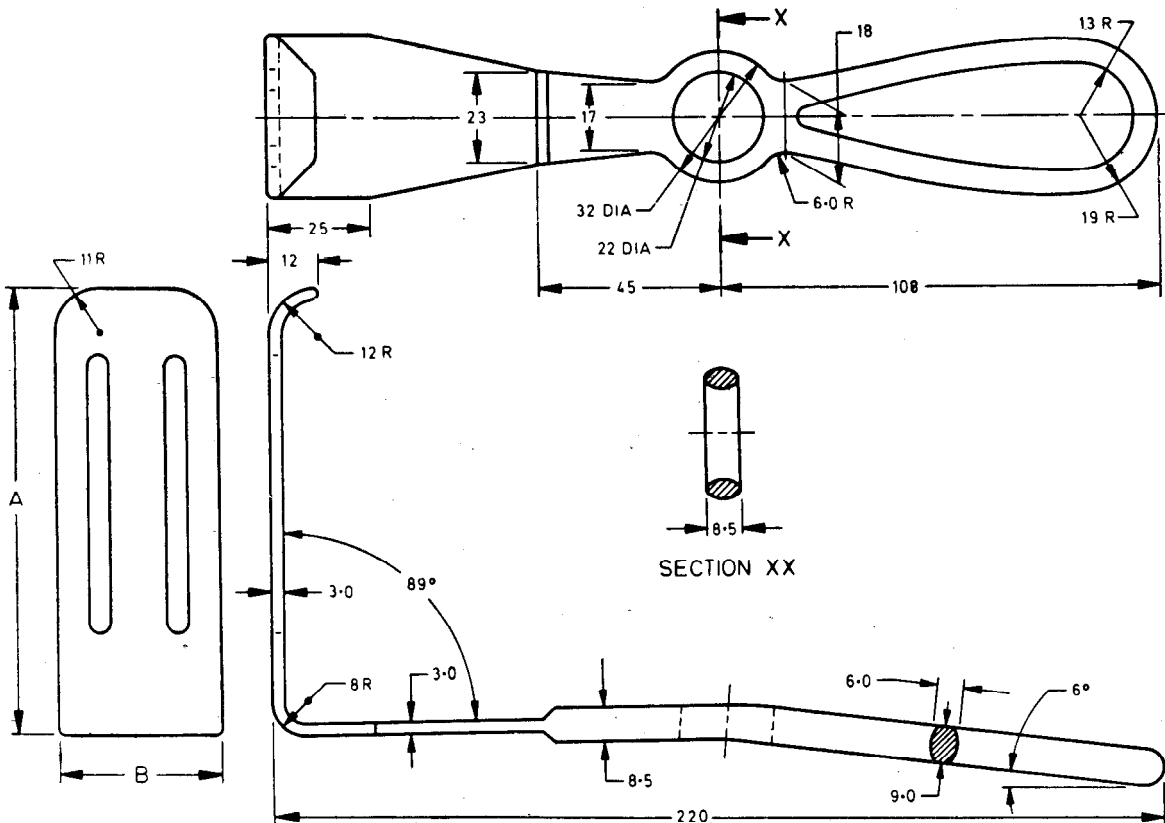
Indian Standard

SPECIFICATION FOR

RETRACTOR, SCAPULA, TUDOR EDWARD'S PATTERN

(First Revision)

1. **Scope** — Specifies requirements and tests for Tudor Edward's pattern scapula retractor used in thoracic surgery.
2. **Material** — Stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS : 6603-1972 'Specification for stainless steel bars and flats'.
3. **Shape and Dimensions** — As shown in Fig. 1.



Size	A	B
Large	115	65
Medium	110	45
Small	80	20

All dimensions in millimetres.

FIG. 1 RETRACTOR, SCAPULA, TUDOR EDWARD'S PATTERN

3.1 Tolerances on linear dimensions shall be in accordance with the following:

- a) ± 0.05 mm on dimensions up to 2.0 mm,
- b) ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm,
- c) ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm,
- d) ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm,
- e) ± 1.0 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- f) ± 2.0 mm on dimensions above 100.0 mm.

3.1.1 Tolerances on angular dimensions shall be as under:

- a) $\pm 1^\circ$ on angles up to 10° , and
- b) $\pm 2^\circ$ on angles greater than 10° .

4. Heat Treatment — The instrument shall be uniformly hardened and tempered to a hardness of 380 to 430 HV, when tested in accordance with IS : 1501 (Part 1)-1984 'Method for Vickers hardness test for metallic materials : Part 1 HV 5 to HV 100 (*second revision*)'.

5. Workmanship

5.1 There shall be no joints in the instrument. It shall be forged in one piece.

5.2 All edges and corners shall be rounded.

6. Surface Condition

6.1 General — All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be supplied free from residual scales, acid, grease, and grinding and polishing materials. Compliance with these requirements shall be checked by inspection using normal vision (corrected, if necessary).

6.2 Surface Finish — The surface finish shall be one of, or a combination of, the following:

- a) Mirror polished;
- b) Reflection-reducing, for example satin finish, matt black finish; and
- c) An applied surface coating, for example for insulation purposes.

Note — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

Instruments to mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be effected by an appropriate procedure, such as polishing, brushing, electropolishing and mirror buffing.

6.3 Passivation and Final Treatment — The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C . The instruments shall then be rinsed in water and dried in hot air.

7. Tests

7.1 Load Test — Hold the retractor by the handle in a vice keeping the bent portion horizontal. Apply gradually a load of 50 N (5 kgf approximately) at the middle of the bent portion. Keep the load for 5 minutes. At the end of the test, the instrument shall not show any sign of damage.

7.2 Corrosion Resistance Test — The instruments shall be tested in accordance with IS : 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. They shall show no sign of corrosion after the test.

8. Marking and Packing

8.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'Stainless Steel' or the letters 'SS'; and the country of manufacture.

8.2 Each instrument shall be put in a polyethylene bag or wrapped in wax paper. The instruments shall then be packed in cartons in accordance with the current trade practice.

8.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

8.3 The packages shall be marked with the name and size of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'Stainless Steel'; and the country of manufacture.

8.4 Certification Marking — Details available with the Bureau of Indian Standards.

9. Sampling — The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Appendix A.

APPENDIX A

(Clause 9)

SAMPLING OF RETRACTORS, SCAPULA, TUDOR EDWARD'S PATTERN

A-1. Lot — In any consignment, all the instruments of same size, produced from identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2. The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING

Lot Size (1)	Sample Size (2)	Sub-Sample Size (3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS : 4905-1968 'Methods for random sampling', may be followed.

A-3. Number of Tests and Criteria for Conformity

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship, and surface condition (visual). An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness, load and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

EXPLANATORY NOTE

This standard was first issued in 1974. In this revision, tolerances on various dimensions have been specified, a recommended sampling plan has been added and the clauses on surface condition have been modified besides incorporating certain other modifications.